PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61L 31/00, A61F 2/02 — A1

(11) International Publication Number: WO 96/40307

(43) International Publication Date: 19 December 1996 (19.12.96)

(21) International Application Number: PCT/US96/08916

(22) International Filing Date: 4 June 1996 (04.06.96)

(30) Priority Data:
08/479,933 7 June 1995 (07.06.95) US

(71) Applicant: W.L. GORE & ASSOCIATES, INC. [US/US]; 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714 (US).

(72) Inventors: VILLALPANDO, Pete, L.; 2609 Jeffrey Loop, Flagstaff, AZ 86004 (US). DAUGHERTY, John, R.; 1647 N. Wood Hollow Way, Flagstaff, AZ 86004 (US).

(74) Agents: CAMPBELL, John, S. et al.; W.L. Gore & Associates, Inc., 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714-9206 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: A TISSUE REPAIR PATCH

(57) Abstract

A tissue repair patch in the form of a biocompatible, flexible sheet of material having a perimeter wherein at least a portion of the perimeter has two or more flanges with a space disposed between adjacent flanges. During repair of a defect in a tissue diaphragm, the patch may be placed so as to cover a hole in the tissue diaphragm with the flanges of the patch placed on both sides of the tissue diaphragm. The patch offers a stronger repair than conventional patches and is anticipated to be useful for hernia repair, for vascular repair, heart muscle repair and for other various soft tissue closures. It may be secured by various known means including sutures and surgical staples.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgystan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic			SE	Sweden
CG	Congo	KR	Republic of Korea	SG	Singapore
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LR	Liberia	SZ	Swaziland
CS	Czechoslovakia	LT	Lithuania	TD	Chad
CZ	Czech Republic	LU	Luxembourg	TG	Togo
DE	Germany	LV	Latvia	TJ	Tajikistan
DK	Denmark	MC	Monaco	TT	Trinidad and Tobago
EE	Estonia	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	UG	Uganda
FI	Finland	ML	Mali	US	United States of America
FR	France	MN	Mongolia	UZ	Uzbekistan
GA	Gabon	MR	Mauritania	VN	Viet Nam

A TISSUE REPAIR PATCH

FIELD OF THE INVENTION

This invention relates to the field of implantable tissue repair patches intended for the repair of living tissue.

BACKGROUND OF THE INVENTION

Implantable patch materials for repair of living tissue defects, particularly for the repair of defects such as inguinal hernias or various other soft tissue defects, have been known for some time. These patch materials are typically made from a single sheet of a flexible, strong, biocompatible polymeric material. Sheets of polypropylene mesh have been used extensively, as have sheets of microporous polytetrafluoroethylene (hereinafter PTFE). One such material is GORE-TEX® Soft Tissue Patch, which is a sheet of porous PTFE having a microstructure of nodes and fibrils with an average fibril length of about 22 microns. The porous microstructure allows adjacent living tissue to grow into the void spaces of the material, forming an attachment to the patch and thereby increasing the strength of the repair.

These conventional patch materials are all in the form of a single sheet of flexible biocompatible material. They are typically attached to only one side of a tissue defect by suturing or by staples.

SUMMARY OF THE INVENTION

The present invention is a tissue repair patch comprising a flexible, biocompatible sheet of material having a perimeter and having two or more flanges around at least a portion of the perimeter. A space is disposed between the flanges whereby the flanges of the patch are placed on either side of the tissue to be repaired. The

flanges are secured to the tissue by conventional means such as by suturing or by stapling.

While the tissue repair patch of the present invention is anticipated to be particularly useful for the repair of structural diaphragms such as in the case of inguinal hernia repairs, it is also anticipated to be useful for repairs of other tissues such as, for example, vascular system repair, repair of heart muscle tissue or for various other soft tissue closures.

The flanged patch of the present invention is also anticipated to be useful as the synthetic patch material intended to close the open end of the skeletal muscle ventricle (SMV) portion of a left ventricular assist device. An LVAD typically comprises a booster pump in series with the arterial output of the heart intended to aid the heart of an individual suffering from chronic congestive heart failure. This booster pump is a skeletal muscle ventricle typically created from a strip of latissimus dorsi muscle rolled up and sewn together to form an open-ended muscle pouch. Two vascular grafts form the inlet and outlet of the pump and connect it to the aorta which is usually ligated between the grafts to force aortic flow through the skeletal muscle ventricle. A circular sheet of synthetic patch material is used to connect the two vascular grafts to the open end of the muscle pouch. These LVAD's and the use of the patch material are described by Thomas GA et al. in an article entitled "Pericardium-Lined Skeletal Muscle Ventricles in Circulation up to 589 Days" (Society of Thoracic Surgeons 1994; 58:1-11).

The patch can be made to have any desired planar shape including circular, ovoid, square and rectangular. The flanges can extend around the entire perimeter of the patch or alternatively may be incorporated into only one or more portions of the perimeter. There may be two flanges or more than two. For example, if the tissue to be repaired included two different layers, then three flanges may be desirable whereby a middle flange is placed between the two layers of tissue with the two outer flanges on either side of the two layers of tissue.

The patch may be made from any biocompatible material with adequate strength and flexibility for the intended repair. While

porous PTFE is believed to be most preferred, other suitable materials include polyethylene terephthalate fabrics and polypropylene meshes.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 describes a combined cross sectional and perspective view of a tissue repair patch having two flanges around the perimeter of the patch.

Figure 2 describes a combined cross sectional and perspective view of a tissue repair patch having three flanges around the perimeter of the patch.

Figure 3 describes a cross sectional view of an apparatus for laminating porous PTFE films to make the inventive patch.

Figures 4A and 4B describe a flanged patch used to connect two vascular grafts to a skeletal muscle ventricle.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 describes a combined cross sectional and perspective view of a tissue repair patch 10 having two flanges 11 and 13 disposed around the perimeter 17 of the patch 10. While the patch illustrated is of circular shape, the patch may be made to have any desired shape including ovoid, square and rectangular. Further, although this illustrated patch includes flanges around the entire perimeter, the flanges may extend around only one or more portions of the perimeter.

Flanges 11 and 13 are located on either side of tissue 15. The central portion of the patch exclusive of the flanges is located within tissue defect 19 intended to be repaired by the patch 10. Attachment of the patch 10 to the tissue 15 is by conventional means such as by sutures or staples placed through the overlapping surfaces of the tissue 15 and patch flanges 11 and 13.

Figure 2 describes a tissue repair patch 10 having three flanges 21, 22 and 23 disposed around the perimeter 17 of the patch 10. Middle flange 22 separates adjacent tissue layers 25 and 26 while

outer flanges 21 and 23 are located on the outer surfaces of tissue layers 25 and 26.

The preferred material for the tissue repair patch is porous PTFE. Porous PTFE having a microstructure of nodes interconnected by fibrils is generally made as described by U.S. Patents 3,953,566 and 4,187,390 to Gore. Porous PTFE of this type for use as implantable patches is preferably expanded by stretching simultaneously in multiple directions within the plane of the material, typically in directions separated by 45 degrees.

The inventive patch is preferably made from two or more layers of porous PTFE sheet material laminated together over the central region of the patch and kept separated over the flanged region to prevent adhesion. By laminated is meant any method of adhesion that accomplishes bonding whereby the laminated surfaces remain laminated together during normal use of the article. Lamination can be accomplished by various means including the use of adhesives such as silicone adhesives and thermoplastic adhesives such as FEP which accomplish lamination by melting of the thermoplastic by the application of heat and pressure to the areas intended to be laminated. A more preferred method involves thermal bonding by applying heat and pressure sufficient to melt-bond the materials comprising the surfaces to be bonded, that is heat and pressure sufficient to melt bond the porous PTFE.

U.S. Patents 4,385,093 and 4,478,665 to Hubis describe methods of laminating porous PTFE; these patents are herein incorporated by reference.

In order to maintain separation of the adjacent layers in the region of the flanges during manufacture, one method involves the use of a separation material to prevent lamination from occurring in the flange region while the central region of the patch is being laminated. One such separation material is Kapton® (DuPont de Nemours, Circleview, OH), a thin, flexible polyimide film that is capable of withstanding the temperatures necessary to melt bond the porous PTFE. This material does not adhere to the porous PTFE during the lamination process.

A preferred method of making the flanged patch is to make it from multiple layers of thin, porous PTFE film. Films of this type, made

as taught by U.S. Patents 3,953,566 and 4,187,390 are particularly strong in their longitudinal direction (the direction they were stretched during manufacture). By stacking these films with their longitudinal directions oriented in various different directions, a patch with high strength in all directions within the plane of the patch is achieved. One or more suitably shaped sheets of Kapton are used within the stack of film as a separation material to create two or more flanges.

The laminating apparatus is described by Figure 3. To construct samples of the sheet material, a vacuum of about 76 cm of water was applied to fixture 43 via port 45. Fixture 43 supports porous metal plate 41 sealed by a gasket 44. The porous metal plate (316L stainless steel, approximately 5 micron pore size, Mott Metallurgical Corp., Farmington CT, part no. 10005-6.5-.5), had a 15 cm diameter circular surface and was of about 1 cm thickness. A sheet of porous, PTFE film 47 having a uniaxial fibrillar orientation was placed over the surface of the porous metal plate 41 so that there were essentially no wrinkles in the film 47, with the vacuum below the porous metal plate 41 holding the film 47 in place. The film used was of about 0.01 mm thickness, about 16.5 cm width and 20 cm length, and had a density of about 0.3 g/cc and a fibril length of about 50 microns. This fibril length is an estimated mean value determined by examining scanning electron photomicrographs of the film surface. The density of solid, non-porous PTFE is generally considered to be about 2.2 g/cc, consequently the film used was about 86% porous by bulk volume. A second layer 48 of the same film was placed over the first layer 47, with the fibrillar orientation of the second layer 48 rotated ten degrees with respect to the fibrillar orientation of the first layer 47. A third layer was then placed over the second, rotated an additional ten degrees. This procedure continued until 18 layers had been stacked together with an equal angular deviation of the fibrillar orientation provided between adjacent film layers. For clarity, Figure 3 describes only a few layers of film. Sheet materials made by this method were thus made in multiples of 18 layers; it is apparent that any number of layers may be used, preferably with an equal angular deviation between the fibrillar

orientation of adjacent layers assuming that uniform strength in all directions within the resulting sheet is desired.

A ring-shaped sheet 61 of Kapton polyimide film was included in the stack of porous PTFE film layers as a separation material to prevent lamination of the adjacent layers of porous PTFE film in the region of the flanges. These adjacent layers of porous PTFE are laminated together in the central region of the patch where the ring-shaped sheet 61 of Kapton polyimide film is open in its respective center region. By this method it is apparent that three or more flanges may be created by the use of two or more sheets of separation material.

After the desired number of layers of film had been provided as described in multiples of 18 layers, a sheet of Kapton polyimide film 49 of about 0.05 mm thickness and of larger length and width than the porous PTFE film sheets, was placed over the stack of film sheets. A circular steel restraining ring 50 was placed over the edges of the polyimide film-covered stack of porous PTFE film. The inside diameter of the retaining ring 50 was of larger diameter than the diameter of the porous metal plate 41 so that only a slight amount of interference existed when even 72 layers of porous PTFE film were used in the stack. A compressive force 55 of about 450 kg was applied to the ring by a Carver laboratory press (model M, Fred Carver Inc., Menomonee Falls, WI). The force 55 was applied via heavy metal plates 51 and 53 heated by electrical cartridge heaters. The temperature of the surface of the polyimide film 49 was monitored by a thermocouple 57 connected to an electronic temperature controller; thirty minutes after reaching an indicated temperature of 365°C, the heated press with metal plates 51 and 53 was removed and the stack of film layers was allowed to cool. The covering sheet of polyimide film 49 was then removed from the laminated stack of porous PTFE film layers along with all ring-shaped sheets 61 of separation material.

The porous PTFE may be made to have pore sizes appropriate for the intended tissue repair depending on whether or not tissue ingrowth is desired. For porous PTFE having a microstructure of nodes interconnected by fibrils, fibril lengths greater than ten microns and more preferably greater than twenty microns are desired to allow tissue ingrowth while fibril lengths of less than fifty microns are

generally preferred for suitable material strength. For applications where tissue ingrowth is not desired, average fibril lengths are preferably less than 10 microns and more preferably less than 5 microns.

The fibril length of porous expanded PTFE that has been expanded in a single direction is defined herein as the average of ten measurements between nodes connected by fibrils in the direction of expansion. Ten measurements are made in the following manner. First, a photomicrograph is made of a representative portion of the sample surface, of adequate magnification to show at least five sequential fibrils within the length of the photomicrograph. Two parallel lines are drawn across the length of the photomicrograph so as to divide the photograph into three equal areas, with the lines being drawn in the direction of expansion and parallel to the direction of orientation of the fibrils. Measuring from left to right, five measurements of fibril length are made along the top line in the photograph beginning with the first node to intersect the line near the left edge of the photograph and continuing with consecutive nodes intersecting the line. Five more measurements are made along the other line from right to left beginning with the first node to intersect the line on the right hand side of the photograph. The ten measurements obtained by this method are averaged to obtain the fibril length of the material.

For a porous, expanded PTFE material that has been expanded in more than one direction, the fibril length is estimated by examining a representative photomicrograph of the material surface and comparing fibril lengths as described above in a manner that represents the various directional orientations of the fibrils.

Figure 4A and the cross sectional view of Figure 4B describe the use of the flanged patch 10 of the present invention to close the open end of the SMV portion 73 of an LVAD 71. The patch is used primarily as a means to connect a pair of vascular grafts 75 and 77 to the SMV 73 via suture lines 81. The two flanges 11 and 13 of the patch 10 are used respectively to attach via suture lines 83 to the pericardium inner lining 85 and the outer skeletal muscle 87 that form the SMV 73. Alternatively, if pericardium 85 is not used to line the SMV 73, then the two flanges 11 and 13 may be attached to either side of the edge of the skeletal muscle 87 used to form the SMV 73.

We Claim:

1. A tissue repair patch comprising a flexible, biocompatible sheet of material having a perimeter, and having at least two flanges around at least a portion of the perimeter with a space disposed between the flanges.
2. A tissue repair patch according to claim 1 wherein the tissue repair patch is comprised of porous polytetrafluoroethylene.
3. A tissue repair patch according to claim 2 wherein the tissue repair patch is a hernia repair patch.
4. A tissue repair patch according to claim 2 wherein the tissue repair patch is a vascular repair patch.
5. A tissue repair patch according to claim 2 wherein the tissue repair patch is a soft tissue closure patch.
6. A tissue repair patch according to claim 2 wherein the tissue repair patch connects a pair of vascular grafts to a left ventricle assist device.
7. A tissue repair patch according to claim 2 wherein the porous polytetrafluoroethylene has a microstructure of nodes interconnected by fibrils.
8. A tissue repair patch according to claim 7 wherein the porous polytetrafluoroethylene has an average fibril length between 10 and 50 microns.
9. A tissue repair patch according to claim 7 wherein the porous polytetrafluoroethylene has an average fibril length less than 10 microns.
10. A tissue repair patch according to claim 1 wherein the tissue repair patch is comprised of polypropylene.
11. A tissue repair patch according to claim 10 wherein the tissue repair patch is a hernia repair patch.
12. A tissue repair patch according to claim 10 wherein the tissue repair patch is a soft tissue closure patch.
13. A tissue repair patch according to claim 1 wherein the at least two flanges extend around the entire perimeter of the tissue repair patch.
14. A tissue repair patch according to claim 13 wherein the tissue repair patch is comprised of porous polytetrafluoroethylene.

15. A tissue repair patch according to claim 1 wherein the tissue repair patch has three flanges.

16. A tissue repair patch according to claim 1 wherein the tissue repair patch is secured to living tissue by sutures.

17. A tissue repair patch according to claim 1 wherein the tissue repair patch is secured to living tissue by staples.

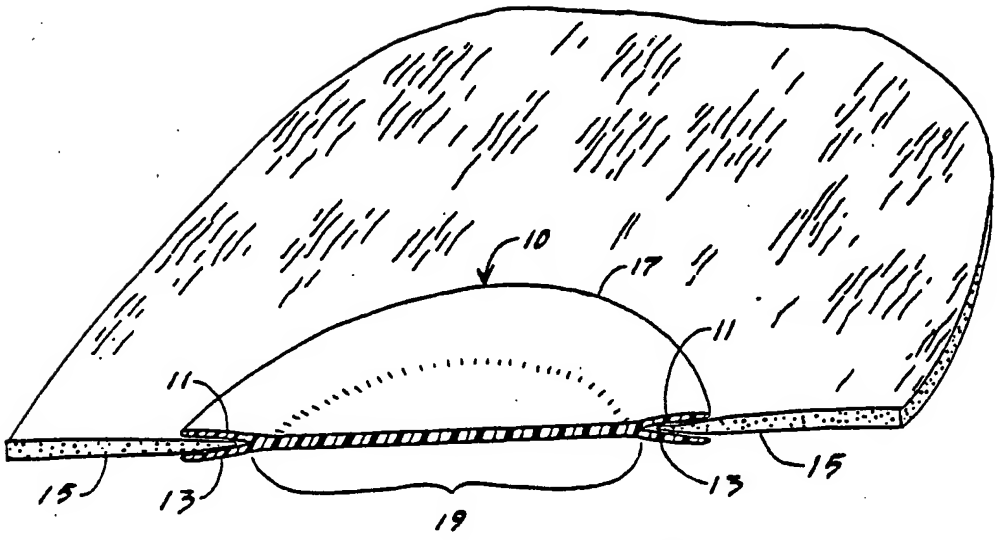

Fig. 1

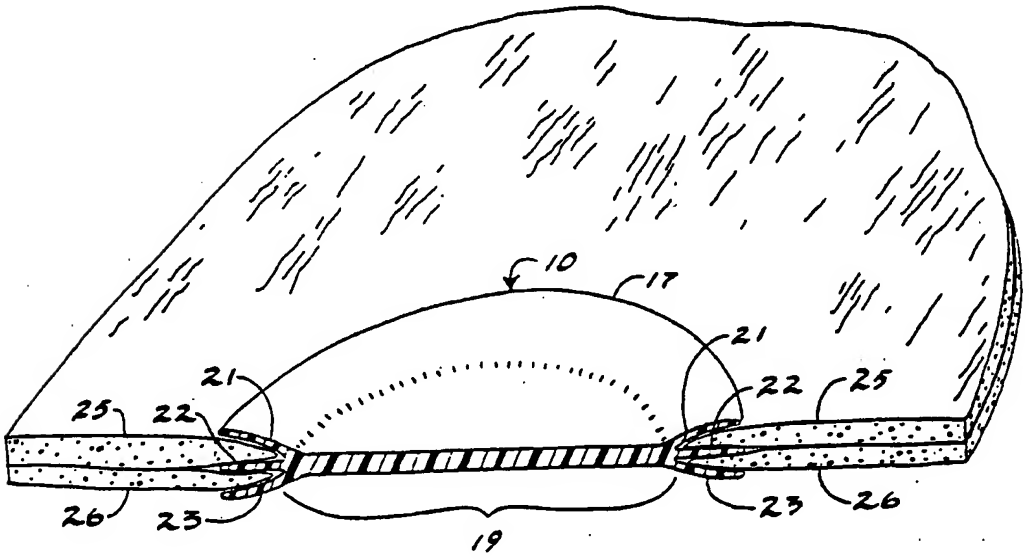

Fig. 2

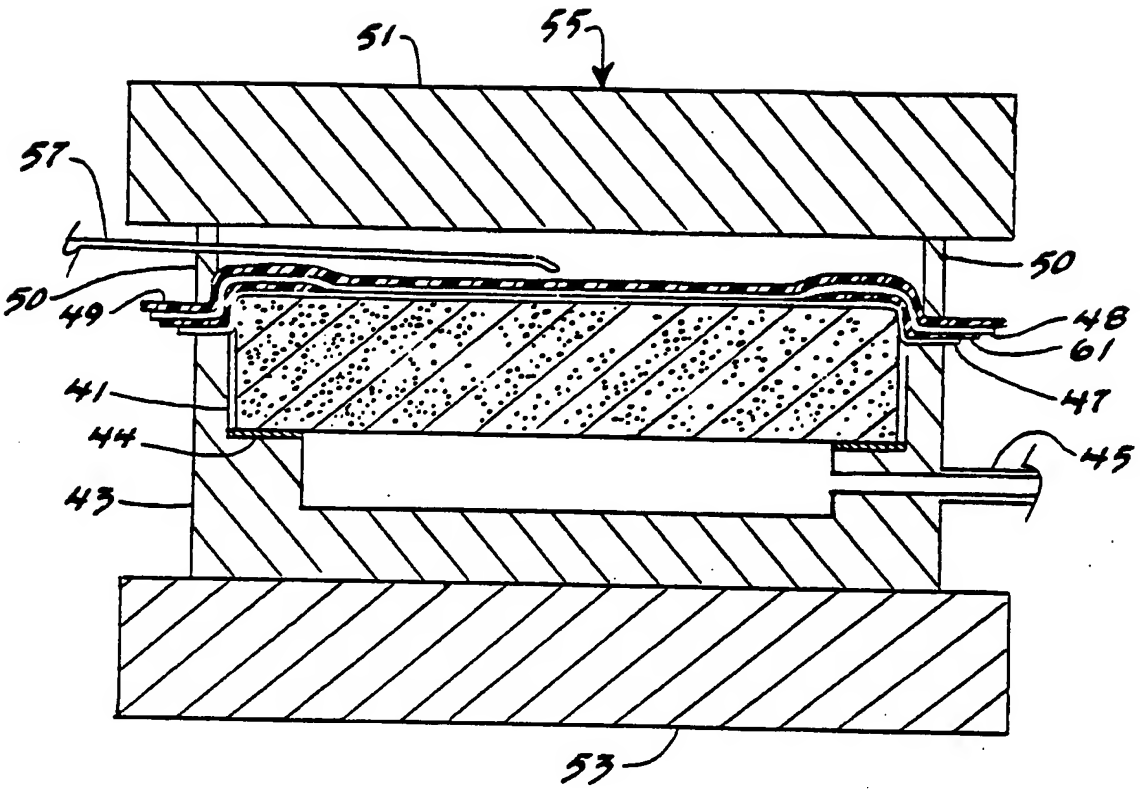

Fig. 3

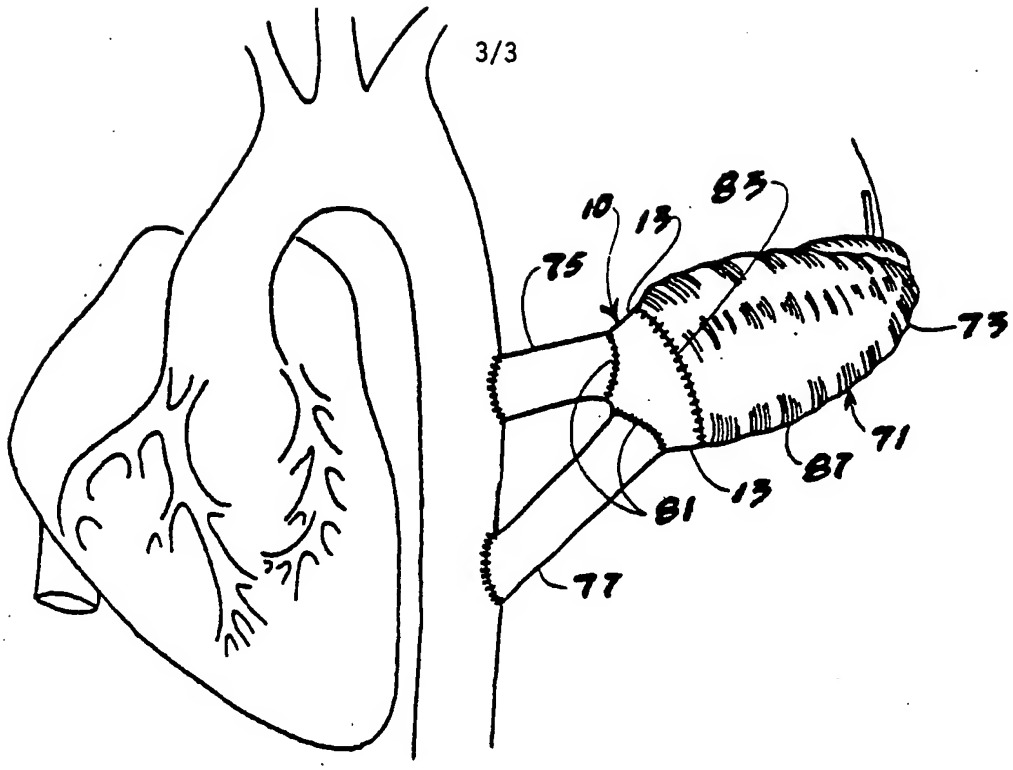

Fig. 4A

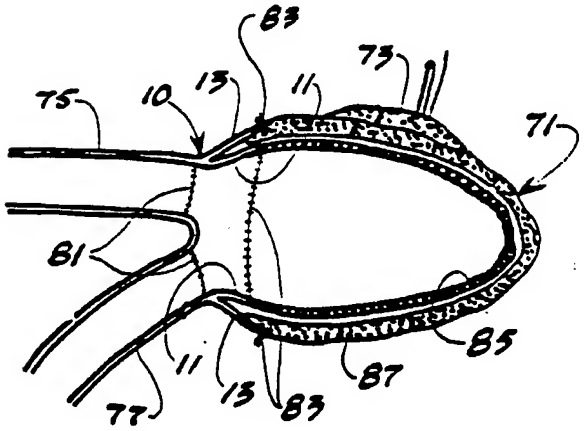

Fig. 4B